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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,115	06/30/2006	Yehiel Ziv	1393GIT-US	5762

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7590 04/22/2010

EXAMINER

HOPKINS, CHRISTINE D

ART UNIT	PAPER NUMBER
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3735

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/585,115	Applicant(s) ZIV ET AL.	
	Examiner CHRISTINE D. HOPKINS	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13, 15 and 16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 13, 15 and 16 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 13 April 2010 has been entered. Claims 1-13, 15 and 16 are now pending. The Examiner acknowledges the amendments to claim 1, as well as the cancellation of claim 14 and the addition of claims 15 and 16.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

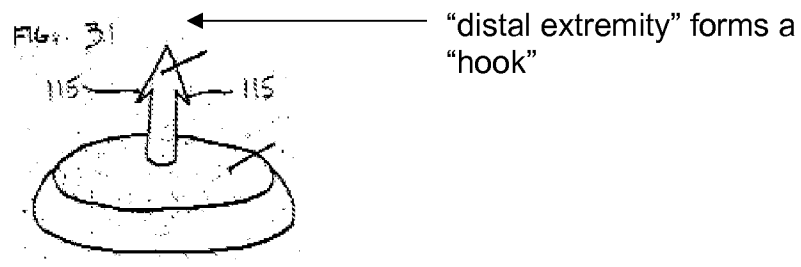
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1, 4-6, 8, 10, 13, 15 and 16 are rejected under 35 U.S.C. 102(e) as being anticipated by Feng et al. (US 6,752,754 B1) in view of Kugler et al. (U.S. Pub. No. 2004/0147801).

Regarding Claims 1, 10, 13, 15 and 16, Feng et al. discloses a gastrointestinal device (artificial rectum 10; Col 3, line 51; Figure 1) comprising: a casing (outer body 16; Col 3, lines 65-66; Figure 1)) comprising fixation elements (connector 32; Col 5, lines

54-56; Figure 1) adapted for intraluminal fixation of the device in the GI tract; a valve (inlet valve 40; Col 4, lines 27-29; Figure 1); and a controller (control unit 15; Col 3, lines 51-59; Figure 1) operatively connected to said valve for externally controlling the position of said valve between the closed and open positions.

However, Feng fails to disclose that the fixation elements are movable between closed and open positions or that the fixation elements have distal extremities that point back towards an outer wall of the casing after entering tissue. Kugler et al. (hereinafter Kugler) teaches a system to be implanted in a tissue conduit for treatment of disorders such as gastrointestinal reflux. Regarding claims 1, 10, 13, 15 and 16, Kugler discloses a device for improving closure or restriction of a body lumen [0006], as similarly disclosed by Feng, comprising a casing **100** and fixation elements **110** ("barbs"), a valve and a controller for controlling the valve [0098]. Kugler further discloses that the fixation elements **110** are resiliently deflected inwardly of the casing ("the first position") and eventually extend from the recesses (or "openings" in accordance with claim 13) of the casing to penetrate the wall of the esophagus for fixation [0095]. The nitinol structure of the fixation elements **110** allows the elements to assume a contracted formation during delivery, and a deployed formation following delivery to the lumen [0083]. Kugler also teaches that the distal extremity of the fixation element may point back towards an outer wall of the casing after entering tissue (see Fig. 31 below).



Such a “hooked” construction resists removal of the device from the tissue in which the spike (distal extremity) has been driven [0133], in accordance with claims 1 and 16. Feng discloses that that connector, or “fixation element” of Kugler may take numerous different configurations, such as staples (col. 7, lines 46-61). Therefore, at the time of the invention it would have been obvious to one of ordinary skill in the art to have constructed fixation elements as taught by Feng, of nitinol material as suggested by Kugler, in order to allow the fixation elements to assume a retracted “first” position for delivery to the lumen and a deployed “second” position for attachment to the lumen. It would have been further obvious to one of ordinary skill in the art to have constructed fixation elements as taught by Feng, with a distal extremity which points back towards an outer wall of the casing (assuming a “hooked” configuration) as taught by Kugler, in order to prevent removal of the device from the patient’s tissue.

Regarding Claim 4, Feng et al. discloses a valve comprising a flexible sleeve which is deformable in the closed and open positions (elastomeric (having the property of being elastic) check valve (Col 5, lines 22-24).

Regarding Claim 5, Feng et al. discloses a controller being a shutter (100 and 102; Figure 6; Col 6, lines 43-67) attached to flexible sleeves, said shutters being selectively movable to cause said flexible sleeve to be in either closed or open positions.

Regarding Claim 6, Feng et al. discloses shutters 100 and 102 being actuated by fluid pressure via pressure sensors (Col. 4, line 61 – Col 5, line 3; Figure 1).

Regarding Claim 8, Feng et al. discloses a controller comprising a fluid inlet 36 (Col 4, line 28; Figure 1) adapted to apply fluid pressure (via pressure sensor) to said flexible sleeves (an increase and decrease in fluid pressure in spring loaded ball-check valve will cause the valve to open and close, thus releasing fluid or air in this instance (Col 5, lines 11-19)) to open and close flexible sleeves.

4. Claims 2-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feng et al. in view of Kugler et al. (U.S. Pub. No. 2004/0147801) as applied to claim 1 above, and further in view of Brooks et al. (US 4,967,844).

Re Claims 2 and 3, the combination of Feng and Kugler discloses all of the claimed elements except for the valve being a ball valve rotatable between closed and open positions and the controller being at least one string attached to the ball valve, so that when the string is pulled, the ball valve rotates. Brooks et al. teaches the ball valve being rotatable between open and closed positions (Col 2, lines 64-66). Brooks et al. also teaches a string being attached to the ball valve assembly so that it rotates when pulled (Col 2, lines 63-68). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to modify Feng and Kugler to include a ball valve (common valve for fluid flow control and Feng et al. states "valve 40 may take the form of any of numerous different types of valves....for performing the function of the valve as described herein." Col 6, lines 64-67) with a string for opening and closing, as taught by Brooks et al., in order to easily and manually control the flow of waste matter through the device.

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5. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Feng et al. in view of Kugler et al. (U.S. Pub. No. 2004/0147801) as applied to claim 4 above, and further in view of Carter et al. (US 5,593,443).

Re Claim 7, the combination of Feng and Kugler discloses all of the claimed elements except for the controller comprising an inflatable member positioned about flexible sleeve, where the inflation and deflation of the inflatable member corresponds with the closing and opening of the flexible sleeve, respectively. Carter et al. teaches a pump and valve 20 and conduit 18 inflate a liquid filled tube (inflatable member) which pressed against the anal canal (effectively, causing the wall to be a "flap" or "flexible sleeve" valve and the inflating and deflating the tube with liquid "opens and closes" the "valve")(Col 5, lines 33-37). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to modify Feng and Kugler to include an inflatable member, as taught by Carter et al., in order to provide an alternative way of controlling flow of fecal matter through the GI tract.

6. Claims 9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Feng et al. in view of Kugler et al. (U.S. Pub. No. 2004/0147801) as applied to claim 1 above, and further in view of Kagan et al. (US 2004/0092892).

Re Claim 9, the combination of Feng and Kugler discloses all of the claimed elements except for the fixation elements being rotatable hooks or barbs. Kagan et al. teaches the use of hooks or other known fasteners (such as barbs, which are used interchangeably with hooks) for attaching a gastrointestinal sleeve device 400 (Figures 23A) into position (Paragraph [0276], lines 8-10). Therefore, it would have been

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obvious to one skilled in the art at the time the invention was made to modify Feng and Kugler to include rotatable hooks as fixation elements, as taught by Kagan et al., in order to secure the gastrointestinal device in position in an alternative way asides from suturing (Figures 23A and 42B).

Re Claim 11, the combination of Feng and Kugler discloses all of the claimed elements except for an insertion assist device adapted to move said fixation elements to a fixed position in the GI tract. Kagan et al. teaches an insertion assist device (surgical instrument 700) placing fixation elements (fasteners 710) into a fixed position (Paragraph [0394], lines 1-9; Figures 49-51). Therefore, it would have been obvious to one skilled in the art at the time the invention was made to modify Feng and Kugler to include the elements of the insertion assist device, as taught by Kagan et al., for the purpose of facilitating the placement of connectors/fixation elements inside the patient's body.

Allowable Subject Matter

7. Claim 12 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Regarding claim 12, while the prior art teaches hooks for fixing a gastrointestinal device to the tissue of the gastrointestinal tract, the prior art of record does not teach or fairly suggest a gastrointestinal device as claimed by Applicant, wherein the insertion assist device comprises a trigger that actuates grabbers to rotate the rotatable hooks (fixation elements).

Response to Arguments

8. Applicant's arguments filed 13 April 2010 with respect to the rejection of claims 1, 4-6, 8, 10 and 13 under 35 U.S.C. 102(e) citing Feng ('754) in view of Kugler ('801) have been fully considered and are not persuasive. Applicant contends that combination does not teach a structure which, after entering the tissue, points back towards the outer wall of the casing. However, this argument is not persuasive. Figure 31 of Kugler displays that the distal extremity of the fixation element may point back towards an outer wall of the casing after entering tissue. The extremity of the fixation element forms a hook, as shown in the figure in the rejection above. In view of the foregoing, the rejection of claims 1, 4-6, 8, 10 and 13 under 35 U.S.C. 102(e) citing Feng ('754) in view of Kugler ('801) has been maintained.

9. Applicant's arguments filed 13 April 2010 with respect to the rejection of claims 2 and 3 under 35 U.S.C. 103(a) citing Feng ('754) in view of Kugler ('801) and further in view Brooks ('844) are contingent upon those presented with regards to claim 1, which are addressed in the response above. In view of the foregoing, the rejection of claims 2 and 3 under 35 U.S.C. 103(a) citing Feng ('754) in view of Kugler ('801) and further in view of Brooks ('844) has been maintained.

10. Applicant's arguments filed 13 April 2010 with respect to the rejection of claim 7 under 35 U.S.C. 103(a) citing 103(a) citing Feng ('754) in view of Kugler ('801) and

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further in view of Carter ('443) are contingent upon those presented with regards to claim 1, which are addressed in the response above. In view of the foregoing, the rejection of claim 7 under 35 U.S.C. 103(a) citing 103(a) citing Feng ('754) in view of Kugler ('801) and further in view of Carter ('443) has been maintained.

11. Applicant's arguments filed 13 April 2010 with respect to the rejection of claims 9 and 11 under 35 U.S.C. 103(a) citing Feng ('754) in view of Kugler ('801) and further in view of Kagan ('892) are contingent upon those presented with regards to claim 1, which are addressed in the response above. In view of the foregoing, the rejection of claims 9 and 11 under 35 U.S.C. 103(a) citing Feng ('754) in view of Kugler ('801) and further in view of Kagan ('892).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINE D. HOPKINS whose telephone number is (571)272-9058. The examiner can normally be reached on Monday-Friday, 7 a.m.-3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. D. H./
Christine D Hopkins
Examiner
Art Unit 3735

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735